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08/894,356	08/18/1997	TOSHIHIKO ASHIKARI	001560-308	8892

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/894,356

Applicant(s)

ASHIKARI ET AL

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on telephone interview on 03/31/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-12,20,22-25,27-41,54-62 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-12,20,22-25,27-41,54-62 and 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 12/07/04 in reply to the Office action of 03/09/04 has been entered. Claims 1, 26, 46-52 and 63 have been cancelled. Claims 2, 5-12, 20, 22-23, 25, 27, 29-33, 36, 55-62 have been amended. New claim 67 has been added. Therefore, 2-3, 5-12, 20, 22-25, 27-41, 54-62, and 64-67 are pending and are considered.

All previous rejections and objections not set forth below have been withdrawn in view of Applicant's amendment.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 as shown in the attached Notice to Comply.

The CRF and paper sequence listing of 08/10/00 have been entered. However, the sequence listings do not comply Rule 1.821, part (c) which requires that each sequence disclosed must appear separately in the "Sequence Listing" and that each sequence set forth in the "Sequence Listing" shall be assigned a separate sequence identifier. According to the sequence listing of 08/10/00, the disclosed nucleotide sequences are identified by SEQ ID NO: 1-6. However, the protein sequences are not listed separately, and no sequence identifier (SEQ ID NO:) has been provided for said

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protein sequences. Applicant is respectfully requested to submit a new Sequence Listing which comprises separate listings of the protein sequences, and to identify the protein sequences by SEQ ID NO:, in response to this Office action.

In response to Applicant's arguments filed in 12/07/04 regarding the previous objection to claims that refer SEQ ID NO: 1-6 as amino acid sequences, it is noted that SEQ ID NO: 1-6 cannot identify both nucleotide sequences and their encoded protein sequences because the search of SEQ ID NO: 1-6 will only pick DNA sequences and not the amino acid sequences. Secondly, the CRF and paper sequence listings of 08/24/00 clearly indicate that SEQ ID NO: 1-6 are DNA sequences and amino acid sequences. Thirdly, Rule 37 CFR 1.821, part (c), requires that each sequence disclosed must appear separately in the "Sequence Listing" and that each sequence set forth in the "Sequence Listing" shall be assigned a separate sequence identifier.

Claims 2-3, 5-6 are objected for failing to further limit parent claim 7 because SEQ ID NO: 22 encoding 21 is not specific to the aromatic acyltransferase of the invention, therefore the sequence further broadens the scope of the polynucleotide. A polynucleotide that hybridizes to a nucleotide sequence encoding SEQ ID NO: 21 does not further limit a polynucleotide encoding a protein having at least 30% or 69% homologous to the protein encoded by SEQ ID NO: 1, 2, 3, 4, 5, or 6. Note, that the protein sequences have to be identified.

Claim Rejections - 35 USC § 112

Claims 2-3, 5-12, 20, 22-25, 27-41, 54-62, and 64-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-8, 28, and 54 are indefinite because SEQ ID NO: 1-6 are DNA sequences rather than amino acid sequences. Dependents 2-3, 5-6, 9-12, 20, 22-25, 27, and 29-41 do not obviate the rejection, therefore are included in the rejection.

Claim 8 is indefinite for depending upon cancelled claim 1. In the interest of compact prosecution, the claim is considered to depend from claim 7.

Claims 5-8 and 28 are indefinite for using various functional languages. For example, claim 7 recites acyltransferase to specific glucose position 3 or 5. However, the functional languages recited in dependent claims 5-6, and 8 appear to broaden the scope of the function of the protein because the acyltransferase activity is not limited to the glucose position 3 or 5. The claims are so confusing in that the functional activity of the protein cannot be clearly determined. It is unclear which function is further limiting which function. It is also unclear why flavonoid and anthocyanin are interchangeably used in the claims. The recitation of a broader (flavonoid) term and a narrower (anthocyanin) in the same claim is indefinite. Because of these various functional languages recited in the claims and the use of flavonoid and anthocyanin in the same claim, the metes and bounds of the claims are unclear. Applicant is suggested to use consistent and clear functional language in the claims.

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Claim 2 is indefinite in the recitation of "using" without positive method steps delimiting how this use is actually practiced. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. This rejection is repeated for the reasons of record as set forth in the last Office action of 03/09/04. Applicant's argument filed 12/07/04 has been considered but is not deemed persuasive. Applicant argues that process steps of "cloning" and "using as a primer" recited in the claims would render the claims definite. This is not persuasive. While examiner agrees with Applicant that cloning is a method step, the phrase "the process of cloning using" as recited in the claim does not imply that "using" is a method step or part of a method step. If Applicant intends that the "cloning" is performed by "using a primer", then "cloning" and "using" are redundant. It is suggested, "using" be deleted.

At claims 11-12 and 31-32 and 57, "said host" lacks antecedent basis. It is suggested that ---cell--- be inserted after "said host".

At claims 11 and 31, "microbial" should be changed to ---microbial cell" for proper Markush language.

At claims 12 and 32, "plant body" is unclear. Applicant argues that plant body simply refers to a plant (response of 12/07/04, p.12). However, since the claim is directed to a host cell, a plant body cannot simply refer to a plant. The term "plant body" is not an art-recognized term and no definition is provided in the specification. Therefore, it is suggested that "a plant body" be deleted.

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Claim 37 is indefinite because "flower" is an organ rather than a tissue. Applicant has neither amended nor argues against this rejection. Also, "tissue" lacks antecedent basis in claim 36, drawn to "a plant, a progeny or tissues thereof" rather than "plant tissue". Appropriate correction is required.

Claim 38 is indefinite in the recitation of "the same property" because it is unclear what property is being referred to. The phrase is not defined in the specification, therefore is open to individual interpretations. Clarification is required to more clearly define the metes and bounds of the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 38 and 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claims are directed to a cutflower from a transgenic plant. The claims do not recite "transgenic" or "transformed" or any phrase that indicates the cutflower retains the polynucleotide introduced into the parent plant. Therefore, the claims read on a product of nature. Due to chimerism, not all cells/tissues/organs of a transgenic plant contain the transgene. The claimed cutflower is indistinguishable from the flower of a naturally growing plant. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. It is suggested that ---transgenic--- be inserted before "cutflower".

Claim Rejections - 35 USC § 112

Claims 2-3, 5-12, 20, 22-25, and 27-41 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for claims limited to the isolated polynucleotide of SEQ ID NO: 1-6, a vector, plant cell/tissue/cut flower, microbial cell, plant comprising it, and a method of transforming a plant with said vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in previous Office actions of 03/09/04 and 02/22/02. Applicant's arguments filed 12/07/04 have been considered but are not deemed persuasive.

Claims 7 and 8 as amended are broadly drawn to an isolated polynucleotide encoding a protein having an amino acid sequence which is at least 30% or 69% homologous (identity, according to the sequence search result when considered with the specification) to SEQ ID NO: 1-6, wherein the protein transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin. Therefore, the scope of the claims encompasses an enormous number of polynucleotides encoding proteins that lack 70% homology with the protein encoded by the polynucleotide sequence of SEQ ID NO: 1-6 (Note, SEQ ID NO: 1-6 are DNA sequences and not amino acid sequences). One skilled in the art would not expect that the majority of said polynucleotides would encode functional proteins having the activity to transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin if the 70% lack of homology falls in regions required for the protein activity. The specification is not enabling for animal cells, and a

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method of transforming said animal cells with exemplified or non-exemplified polynucleotides.

Claims 2-3, depending from claim 7, are drawn to said polynucleotide produced by cloning with the primer SEQ ID NO: 22 or with a nucleotide sequence encoding SEQ ID NO: 21. However, SEQ ID NO: 21 and 22 are only 6 amino acids and 17 nucleotides, respectively, in length; and are not specific to proteins that transfer an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin. A sequence search result of SEQ ID NO: 21 reveals that non-anthocyanin acyltransferase proteins also contain SEQ ID NO: 21 (see attached Sequence Search results, Accession no: T45574; T00527; and T03224, pages 1-4).

Claims 5-6, depending from claim 7, are drawn to said polynucleotide which hybridizes with a nucleotide sequence encoding SEQ ID NO: 21 or the nucleotide sequence of SEQ ID NO: 1-6 under the hybridization conditions of 2XSSC or 5XSSC and 50°C, wherein the polynucleotide encodes a protein that transfers an aromatic acyl group to flavonoid. However, the hybridizing property of a nucleic acid cannot be used to predict the functional activity of the nucleic acid. In addition, the hybridization conditions as recited in the claims fail to specify wash time, therefore, any nucleotide sequence can hybridize to SEQ ID NO: 1-6 for a short period of time. In addition, the conserved sequence of SEQ ID NO: 22 or 21 is not specific to the aromatic acyltransferases that transfer to the glucose of the 3 or 5 position of anthocyanin as discussed above. Therefore, the use of these hybridization conditions and SEQ ID NO:

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22 are not expected to yield polynucleotides that are functionally related to the polynucleotides of SEQ ID NO: 1-6, absent evidence to the contrary.

Claim 28 is broadly drawn to an isolated polynucleotide that hybridizes with the complementary polynucleotide encoding the amino acid sequence of SEQ ID NO: 1-6, under the hybridization conditions of 5XSSC and 50°C or the 2XSSC and 50°C, wherein the hybridizing polynucleotide encodes an anthocyanin acyltransferase that transfers an aromatic acyl group to flavonoid. However, neither Applicant's specification nor the prior art provides evidence that the hybridizing property of a polynucleotide is sufficient for a skilled artisan to predict the function of the polynucleotide. Note, SEQ ID NO: 1-6 are not amino acid sequences.

Response to Arguments

The scope of enablement rejection is maintained. Applicant argues that claims 7 and 28 are enabled because the claims as amended recite structural features that are defined homology and hybridization property and recite functional property that are common to the members of claimed genus of polynucleotides. Therefore, Applicant asserts, given this defined relationship among the members of the claimed genus, the scope of the claims corresponds to the scope of enablement, in accordance with 35 USC 112, 1st paragraph (response, p. 15, 2nd full paragraph).

These are not persuasive because the specification does not provide guidance for how to make and use polynucleotides other than SEQ ID NO: 1-6 having the structural and functional properties as recited in the claims. Applicant's arguments regarding defined common structural and functional properties among members of the

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claimed genus are written description issues rather than enablement issues. The test of enablement is "how to make and use" and the test of scope of enablement is whether the enabling disclosure is commensurate in scope with the claims, and that one skilled in the art can practice the full scope of the claimed invention without undue experimentation. The instantly claimed invention is broader than the enabling disclosure, and one skilled in the art will not be able to practice the full scope of the claims without undue experimentation, for the reasons of record as set forth set forth in the last Office actions of 03/09/04 and 02/22/02.

Applicant also argues that the instant specification, pages 5 and 6, teaches the full scope of the polynucleotide of claims 7 and 28, and Applicant refers to the DNA encoding the amino acid sequences of SEQ ID NO: 1-6 (Note, SEQ ID NO: 1-6 are DNA sequences), and the use of said DNAs and SEQ ID NO: 21 and 22 as probes to obtain additional DNA falling within the scope of the claims (response, paragraph bridging pages 15 and 16).

This is not persuasive. Pages 5 and 6 of the specification teach cloning of the nucleic acids of SEQ ID NO: 1-6 from gentians, petunias, cineraria, perilla, and lavenders. However, the nucleic acids recited in claims 7 and 28 extend far beyond the SEQ ID NO: 1-6. In addition, the conserved region of SEQ ID NO: 22 encoding 21 is not specific to the aromatic acyltransferase gene/protein family and the hybridization conditions as recited in the claims defines low stringency and lacks wash time.

Applicant further argues that the specification enables the claimed genus by demonstrating a representative number of working workings. Applicant refers to

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Examples 6, 8 11-12 and 20. Applicant further argues that using said disclosed sequences, one skilled in the art could readily obtain other anthocyanin acyltransferase polynucleotides as encompassed by the claims. Applicant argues that conservative modifications of sequences are known in the art, and do not constitute undue experimentation (response, pp. 16-17).

This is not persuasive. While the specification teaches several examples of isolating DNA of acetyltransferase from five different flower species, this does not address the fact the specification has not taught one skilled in the art how to make and use the polynucleotides as broadly claimed. It is highly unpredictable if all the polynucleotides that hybridize to SEQ ID NO: 1-6 would encode functional proteins having the activity to transfer an aromatic acyl group to 3 or 5 position of anthocyanin. Furthermore, the hybridization conditions as recited in the claims were not even used for the isolation of the exemplified sequences. For example, in Example 8, the cDNA cloning of acyltransferase from petunia was carried a washing of 0.2 X SSC at 65°C for 1 hr. For the cloning of cDNA from perilla in Example 11, washing was carried out in 1 XSSC at 65°C for 1hr.

With regard to the conservative modifications, the state of the prior art teaches that results of conservative modifications are not predictable. For example, Lazar et al (Mol. Cell. Biol., Vol. 8, pp. 1247-1252, 1988(U)) teach that the conservative substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha, while "nonconservative" substitutions with alanine or asparagine had no effect (see at least the Abstract). There is also a complete lack of

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guidance in the specification and in the prior art as to how and where the disclosed sequences or sequences having anthocyanin acyltransferase activity can be modified while retaining the desired activity. Given this highly unpredictable areas and lack of sufficient guidance in the specification, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of polynucleotides encoding proteins with multiple of amino acid modifications to identify those having the functional activity of the protein encoded by SEQ ID NO: 1-6.

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997) states. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The *Genentech* court also held that [w]hile every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". Id. In this case, as in *Genentech*, the specification does not provide the "reasonable detailto enable members of the public to understand and carry out the invention as broadly claimed".

See also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. In this case, the disclosure of SEQ ID NO: 1-6 encoding proteins having the activity to transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin does not enable any variant thereof that retains the enzyme activity.

See also *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it states " the scope of enablement must bear a "reasonable correlation" to the scope of the claims. In the instant case, the scope of the claims does not reasonably correlate to the scope of enablement.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra and in the last Office actions; the unpredictability with regard to amino acid modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope (*In re Wands* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

Written Description

Claims 2-3, 5-12, 20, 22-25, and 27-41 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in previous Office actions of 03/09/04 and 02/22/02. Applicant's arguments filed 12/07/04 have been considered but are not deemed persuasive.

The written description rejection is maintained. Applicant argues that the claims as amended recite structural features that are defined homology and hybridization property and recite functional property that are common to the members of claimed genus of polynucleotides. Therefore, Applicant asserts, given this defined structural

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relationship among the members of the claimed genus, the claimed invention is adequately described. Applicant also argues against the reliance of *Eli Lilly*, and Applicant points to Example 9 of the Written Description Guidelines, which address the issue of hybridization.

These are not persuasive because the specification does not describe a representative number of polynucleotides of the genus claimed. The hybridization conditions as recited in the claims is incomplete and define low stringency at the most, and the conservative sequence of SEQ ID NO: 21 or 22 is not specific to the protein family that transfers an aromatic acyl group to the glucose of the 3 or 5 position of anthocyanin. Given the vast number of polynucleotides encompassed by the claimed genus and the expected variation in structures and function within members of said genus polynucleotides due to the non-specific conservative sequences of SEQ ID NO: 21 or 22, and the hybridization conditions of the claims; The description of SEQ ID NO: 1-6 are insufficient to provide adequate written description for the claimed genus. This is exactly the same situation as in *Eli Lilly*, where the court stated "(A) description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus" (43 USPQ2d at 1406).

Regarding example 9 of the Synopsis of Application Guidelines for Written Description, it is noted that the two situations are not analogous because the generic claim in Example 9 recites high stringent conditions. In addition, in Example 9, the

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specification includes an example wherein the complement of the disclosed sequence was used to obtain nucleic acids encoding functional proteins. In the instant claims, the hybridization conditions as recited in the claims define low stringency, and none of the disclosed sequences was obtained under such conditions.

Remarks

Claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide encoding a protein that is at least 30% homologous to the protein encoded by SEQ ID NO: 1-6, host cells, plants/plant cells comprising said polynucleotide; nor that the prior art teaches a method that employs said polynucleotides.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mai
3/6/05

MEDINA A. IBRAHIM
PATENT EXAMINER
